



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/593,316 06/13/00 CLARK

J 730/002

022869  
GERON CORPORATION  
230 CONSTITUTION DRIVE  
MENLO PARK CA 94025

HM12/0925

EXAMINER

LLU

ART UNIT

PAPER NUMBER

1632  
DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/593,316

Applicant(s)

CLARK ET AL.

Examiner

Q. Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

## DETAILED ACTION

Claims 1-32 are pending in the application.

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1-5 are drawn to an ovine tissue and/or cells devoid of antibody-detectable Gala(1,3) determinants, heterozygous or homozygous for inactivation of a  $\alpha$ 1,3GT gene. Classified in class 424, subclass 93.21.
- II. Claims 6 and 13-15 are drawn to an ovine animal homozygous for inactivation of a  $\alpha$ 1,3GT gene, and methods of producing the animal and harvesting cells from the animal. Classified in class 800, subclass 13.
- III. Claims 7-12, 17-21, 27 are drawn to a polynucleotide construct effective for inactivating a  $\alpha$ 1,3GT in an ovine cell and a method for inactivating  $\alpha$ 1,3GT expression by a cell using such construct. Classified in class 536, subclass 23.1, and class 435, subclass 463.
- IV. Claim 16 is drawn to a method of xenotransplantation. Classified in class 424, subclass 423.
- V. Claims 22-26 are drawn to a polypeptide contained in SEQ. ID No:2. Classified in class 530, subclass 300.

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- VI. Claims 28, 30, and 32 are drawn to an isolated antibody and a method of producing such, and a method of using the antibody for assays. Classified in class 530, subclass 387.1, and class 435, subclass 7.1.
- VII. Claim 29 is drawn to a hybridization assay method using mRNA or cDNA of  $\alpha 1,3$ GT gene. Classified in class 435, subclass 6.
- VIII. Claim 31 is drawn to a method for preparing a  $\alpha 1,3$ GT. Classified in class 530, and subclass 350.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II-VIII and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, groups I, II, IV, V, and VI are drawn to different products, namely, cells, an transgenic animal, polynucleotides, polypeptides and antibodies, which have distinct chemical and biological structure, different methods of making and using the distinct products. Groups II and I are distinct, because cells of group I could be obtained using a method other than harvesting from the animal in group II. Groups II-IV, VI-VIII comprise different methods of making and using transgenic animals, antibodies, using polynucleotides for cell transformation or for diagnosis, etc. These methods use different protocol, different test criteria, have different method steps, different modes of operation, and have distinct technical considerations. The differences of the Inventions

I-VIII are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if examined together, thus, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

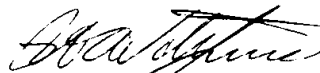
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen M Hauda can be reached on 703-305-6608. The fax numbers for the organization where this application or proceeding is assigned are 703-308-8724 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Kay Pinsky, whose telephone number is (703) 305-3553.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li  
Examiner  
Art Unit 1632

QJL  
September 19, 2001

  
ROBERT A. SCHWARTZMAN  
PRIMARY EXAMINER